UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Case No.: 0:15-cv-00176

MARIAN O'NEILL,

Plaintiffs,

vs.

DAIICHI SANKYO, INC., d/b/a Sankyo USA Development, Sankyo Pharma Development, Sankyo Pharma, Inc., Daiichi Sankyo Pharma Development, Daiichi Pharmaceuticals, Inc., Daiichi Medical Research Institute, Inc., Daiichi Pharma Holdings, Inc.,

And

DAIICHI SANKYO U.S. HOLDINGS, INC., parent company of Daiichi Sankyo, Inc.,

And

FOREST LABORATORIES, LLC, f/k/a Forest Laboratories, Inc.,

And

FOREST PHARMACEUTICALS, INC.,

And

FOREST RESEARCH INSTITUTE, INC.,

Defendants.

COMPLAINT
AND
DEMAND FOR JURY TRIAL

Plaintiff, Marian O'Neill, for her cause of action against the above-named Defendants, allege(s) and state(s) on information and belief as follows:

INTRODUCTION

Plaintiff, Marian O'Neill, brings this action for personal injuries suffered by Plaintiff , Marian O'Neill, as a proximate result of Benicar® being prescribed and ingesting the defective and unreasonably dangerous pharmaceutical blood pressure medication containing the drug olmesartan medoxomil, which is and was at all times relevant to this action, manufactured, designed, researched, tested, packaged, labeled, marketed, advertised, distributed, prescribed, and sold by Defendants identified herein. Plaintiff(s) allege(s) as follows:

PARTIES

Plaintiff(s)

1. Plaintiff Marian O'Neill is an adult individual is and was, at all times relevant to this action, a citizen and resident of the city of Duluth, county of Saint Louis, State of Minnesota. Plaintiff brings this action against Defendants for the personal injuries she suffered as a result of ingesting the pharmaceutical drug containing olmesartan medoxomil, which Plaintiff believes and alleges is and was designed, compounded, manufactured, researched, tested, marketed, advertised, labeled, distributed, sold, packaged or promoted by the Defendants identified in this Complaint.

2. Plaintiff(s) claim and allege that their damages and injuries are the direct and proximate result of Defendants' negligent, intentional, and wrongful acts, omissions, and conduct regarding Defendants' design, development, formulation, manufacture,

testing, packaging, labeling, promotion, advertising, marketing, distribution and sale of products containing the drug olmesartan medoxomil.

Defendants

A. Daiichi Sankyo Defendants

4. On information and belief, Defendant Daiichi Sankyo, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business located at Two Hilton Court, Parsippany, New Jersey 07054.

5. On information and belief, Daiichi Sankyo, Inc. is or was also known as Sankyo USA Development, Sankyo Pharma Development, Sankyo Pharma Inc., Daiichi Sankyo Pharma Development, Daiichi Pharmaceuticals, Inc., Daiichi Medical Research, Inc., and Daiichi Pharma Holdings, Inc.

6. On information and belief, Daiichi Sankyo, Inc. is in the business of designing, marketing, researching, distributing, packaging, marketing, promoting and selling pharmaceutical drugs across the United States, including within the State of MINNESOTA.

7. On information and belief, Daiichi Sankyo, Inc. has a development and regulatory group named Daiichi Sankyo Pharma Development with offices in Edison, New Jersey, and a research institute named Daiichi Sankyo Research Institute with offices in Edison, New Jersey.

8. On information and belief, Daiichi Sankyo U.S. Holdings, Inc. is a Delaware corporation and has a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054.

9. On information and belief, Daiichi Sankyo, Inc. is a wholly owned subsidiary of Daiichi Sankyo U.S. Holdings, Inc.

10. On information and belief, Daiichi Sankyo U.S. Holdings, Inc. operates as a holding company for Daiichi Sankyo Co., Ltd.

11. There existed, at all relevant times to this action, a unity of interest in ownership between Daiichi Sankyo, Inc., and Daiichi Sankyo U.S. Holdings, Inc., such that any independence from, and/or separation between and among the Defendants has ceased and/or never existed; in that these two Defendants, and each of them are the alter egos of one another and exerted direct control over each other. Adherence to the fiction of a separate and independent existence among the two Defendants, as separate entities distinct from one another will permit an abuse of the corporate privilege, sanction a fraud upon the plaintiff and other consumers of their products containing olmesartan medoxomil, and promote injustice. The two Defendants, and each of them, condoned and ratified the negligent, willful, intentional, and wrong acts, omissions, and conduct of each other.

12. For convenience purposes Daiichi Sankyo, Inc., and Daiichi Sankyo U.S. Holdings, Inc., are hereinafter collectively referred to as "Daiichi Sankyo."

13. On information and belief, Daiichi Sankyo designs and manufactures numerous pharmaceutical drugs for sale and use through the United States, including within the State of MINNESOTA.

14. On information and belief, Daiichi Sankyo designed, manufactured, packaged, labeled, distributed, sold, marketed, advertised, and/or promoted the blood pressure drugs containing olmesartan medoxomil, which is marketed in the United States as Benicar®, Benicar HCT®, Azor®, and Tribenzor®. Daiichi Sankyo refers to these drugs collectively as the "Benicar Family."

B. Forest Defendants

15. On information and belief, Forest Laboratories, LLC ("Forest Labs"), formerly known as Forest Laboratories, Inc., is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Forest Labs is in the business of manufacturing, distributing, marketing or promoting numerous pharmaceutical drugs for sale and use throughout the United States, including within the State of MINNESOTA.

16. On information and belief, Forest Pharmaceuticals, Inc. ("Forest Pharmaceuticals") is incorporated in Delaware with its principle place of business located at 13600 Shoreline Drive, St. Louis, Missouri. At all times relevant to this action, Defendant Forest Pharmaceuticals is and has been a division and wholly owned subsidiary of Forest Labs responsible for the manufacture, distribution, and sales of prescription medicine for Forest Labs.

17. On information and belief, Forest Research Institute, Inc. ("FRI"), is a wholly-owned subsidiary of Forest Laboratories, Inc., and is incorporated in New Jersey with its principal place of business at Harborside Financial Center, Plaza V, Suite 1900, Jersey City, New Jersey. At all times hereinafter mentioned, Defendant FRI was and still is a pharmaceutical entity involved in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public of drug medicine, throughout the United States.

18. There existed, at all relevant times to this action, a unity of interest in ownership between Forest Labs, Forest Pharmaceuticals, and FRI, such that any independence from, and/or separation between and among the Defendants has ceased and/or never existed; in that these Defendants, and each of them are the alter egos of one another and exerted direct control over each other. Adherence to the fiction of a separate and independent existence among the three Defendants, as separate entities distinct from one another will permit an abuse of the corporate privilege, sanction a fraud upon the plaintiff and other consumers of the olmesartan products, and promote injustice. The three Defendants, and each of them, condoned and ratified the negligent, willful, intentional, and wrong acts, omissions, and conduct of each other.

19. For convenience purposes, Defendants Forest Labs, Forest Pharmaceuticals and FRI are hereinafter referred collectively as "Forest."

20. On information and belief, Defendants Forest and Daiichi Sankyo entered an expense and profit sharing relationship in exchange for the co-promotion of blood pressure drugs containing olmesartan medoxomil, including but not limited to

Benicar®, Benicar HCT®, Azor®, and Tribenzor® (hereinafter collectively referred to as the "olmesartan products").

21. On information and belief, Forest profited from the olmesartan products, receiving 45 percent of Benicar profits for several years in exchange for its co-promotion of the products.

C. All Defendants

22. The term "Defendants" is used hereafter to refer to all the entities named above.

23. Defendants are corporations organized under the laws of various states of the United States of America that were or are doing business within the State of MINNESOTA. The aforementioned Defendants designed, marketed, sold, distributed, packaged, promoted, labeled, researched, tested or manufactured the olmesartan product(s) which Plaintiff ingested.

24. At all times relevant to this action, all Defendants and each of them were in the capacity of the principal or agent of all of the other Defendants, and each of them, and acted within the scope of their principal and agent relationships in undertaking their actions, conduct, and omissions alleged in this Complaint. All Defendants, and each of them, acted together in concert or aided and abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of reaping substantial monetary profits from the sale of the olmesartan products and for the purpose of enriching themselves financially to the serious detriment of Plaintiffs' health and well being.

JURISDICTION AND VENUE

25. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

26. At all times relevant to this action, the Defendants have been engaged either directly or indirectly in the business of marketing prescription drug products, including the olmesartan products, within the State of MINNESOTA, with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

27. At all times relevant to this action, the Defendants have been engaged either directly or indirectly in the business of promoting prescription drug products, including the olmesartan products, within the State of MINNESOTA, with a reasonable expectation that the products would be used or consumed in this state, and thus have regularly solicited or transacted business in this state.

28. At all times relevant to this action, the Defendants have been engaged either directly or indirectly in the business of distributing prescription drug products, including the olmesartan products, within the State of MINNESOTA, with a reasonable expectation that the products would be used or consumed in this state, and thus have regularly solicited or transacted business in this state.

29. At all times relevant to this action, the Defendants have been engaged either directly or indirectly, in the business of selling prescription drug products, including the olmesartan products, within the State of MINNESOTA, with a reasonable

expectation that the products would be used or consumed in this state, and thus have regularly solicited or transacted business in this state.

30. At all times relevant to this action, the Defendants were engaged in disseminating inaccurate, false, and misleading information about the olmesartan products to physicians in all states in the United States, including the State of MINNESOTA, with a reasonable expectation that the misleading information would be used and relied upon by physicians throughout the United States, including the State of MINNESOTA.

31. Defendant Daiichi Sankyo, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in New Jersey. Accordingly, for purposes of diversity jurisdiction, it is a citizen of Delaware and New Jersey.

32. Defendant Daiichi Sankyo U.S. Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in New Jersey. Accordingly, for purposes of diversity jurisdiction, it is a citizen of Delaware and New Jersey.

33. Defendant Forest Laboratories LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business in New Jersey. Tango US Holdings, Inc. is the sole member of Forest Laboratories, LLC. Tango US Holdings, Inc. is incorporated in Delaware. In filings with the SEC, contact information for Tango US Holdings, Inc. is listed as "c/o Actavis plc, Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054." According to this

same filing, Tango US Holdings, Inc. was incorporated on February 13, 2014 for the purposes of effecting the merger between Forest Laboratories, Inc. and Actavis, and to date, it has "not conducted any activities other than those incidental to its formation, the execution of the Merger Agreement, the preparation of applicable filings under U.S. securities laws and regulatory filings made in connection with the proposed transaction." SEC Schedule 14A, publicly available at http://www.sec.gov/Archives/edgar/data/38074/000119312514182901/d686059ddefm14a.htm. In its Amended and Restated Certificate of Incorporation, Tango US Holdings, Inc. identified its registered office as being located in Wilmington, Delaware. Therefore, Tango US Holding, Inc.'s principal place of business is either in New Jersey or in Delaware, and for purposes of diversity jurisdiction, it is a citizen of New Jersey and Delaware.

34. Defendant Forest Laboratories, LLC, for purposes of diversity jurisdiction, has the citizenship of its member, Tango US Holdings, Inc., and is therefore a citizen of Delaware and New Jersey.

35. Defendant Forest Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Missouri. Accordingly, for purposes of diversity jurisdiction, it is a citizen of Delaware and Missouri.

36. Defendant FRI is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. Accordingly, for purposes of diversity jurisdiction, it is a citizen of New Jersey.

37. This action is properly before the Court because there is complete diversity of citizenship between plaintiff and defendants. In addition, the amount in controversy claimed by plaintiff exceeds $75,000. As a result, this Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).

38. Venue is proper within this District pursuant to 28 U.S.C. § 1391 Defendants are subject to personal jurisdiction within this District in accordance with 28 U.S.C. §1391(c), in that Defendants did and do business within and have continuous and systematic contacts with the state of MINNESOTA, have consented to jurisdiction in the state of MINNESOTA and/or committed a tort in whole or in part in the state of MINNESOTA against Plaintiff, as more fully set forth herein. On information and belief, defendants also advertised in this district, made material omissions and representations in this district, and breached warranties in this district.

FACTUAL BACKGROUND

39. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

40. At all times relevant to this action, Defendants acted through their respective officers, employees and agents, who in turn were acting within the scope of their authority and employment in furtherance of the business of the Defendants.

41. On information and belief, olmesartan medoxomil is classified as an angiotension II receptor blocker ("ARB"). At all times relevant to this action, there were seven commercialized ARB monotherapy products available. Olmesartan medoxomil was the seventh and last to the ARB market.

42. On information and belief, Daiichi Sankyo, Inc., f/k/a Sankyo Pharma, holds an approved new drug application ("NDA'') No. 21-286 for Benicar® tablets (5 mg, 20 mg, and 40 mg), which tablets contain the active ingredient olmesartan medoxomil. Benicar® tablets were approved by the United Stated Food and Drug Administration ("FDA") on April 25, 2002, for treatment of hypertension.

43. On information and belief, Daiichi Sankyo, Inc., f/k/a Sankyo Pharma, holds an approved NDA No. 21-532 for Benicar HCT® tablets (40/12.5 mg, 40/25 mg, and 20/12.5 mg), which tablets contain the active ingredients olmesartan medoxomil and hydrochlorothiazide. Benicar HCT® tablets were approved by the FDA on June 5, 2003, for the treatment of hypertension, but are not indicated for initial therapy.

44. On information and belief, Daiichi Sankyo, Inc. holds an approved NDA No. 22-100 for Azor® tablets (5/20 mg, 5/40 mg, 10/20 mg, and 10/40 mg), which tablets contain the active ingredients amlodipine besylate and olmesartan medoxomil. Azor® tablets were approved by the FDA on September 26, 2007 for the treatment of hypertension, alone or in combination with other antihypertensive agents.

45. On information and belief, Daiichi Sankyo, Inc. holds an approved NDA No. 20-0175 for Tribenzor® tablets (40/10/25 mg, 40/5/12.5 mg, 20/5/12.5 mg, 40/5/25 mg, 40/10/12.5 mg), which tablets contain the active ingredients olmesartan medoxomil, amlodipine and hydrochlorothiazide. Tribenzor® tablets were approved by the FDA on July 23, 2010, for treatment of hypertension, but are not indicated for initial therapy.

46. The terms "Benicar" and "olmesartan" are frequently and interchangeably employed, in common usage among the medical community, to refer to all or any of the olmesartan medoxomil products, including the specific brand name products Benicar®, Benicar HCT®, Azor®, and Tribenzor®.

47. On information and belief, Daiichi Sankyo refers to its olmesartan medoxomil products as the "Benicar Family."

48. For convenience purposes, the olmesartan medoxomil products sold by Defendants are hereinafter collectively referred to as "olmesartan products."

49. As required by law for all prescription drug products, each of the Defendants include the product's "labeling," as approved by the FDA, on labels, also called "package inserts," placed on or in the packages from which the products were to be dispensed from pharmacies, or from which "product samples," if any, were to be dispensed by doctors. The labeling includes information on the product's active and inactive ingredients, clinical pharmacology, "indications" and usage, contraindications, warnings, precautions, and side effects (adverse reactions and overdosage).

50. The "indications" or "indicated" uses for the olmesartan products, as reflected in the product labeling, included treatment of hypertension, alone or with other antihypertensive agents, to lower blood pressure.

51. The text of the "indications" or "indicated" uses for the olmesartan products did not disclose any risks associated with long-term use of the drug.

52. The package inserts for the olmesartan products are materially identical to the "monograph" for the olmesartan products published in the Physician's Desk Reference.

53. In connection with all of the olmesartan products, Plaintiffs allege the following:

FDA Drug Safety Communication and Label Change

54. On July 3, 2013, the FDA issued a Drug Safety Communication warning that the blood pressure drug olmesartan medoxomil, marketed as Benicar®, Benicar HCT®, Azor®, and Tribenzor®, can cause intestinal problems known as sprue-like enteropathy. The FDA approved changes to the label of these drugs to include this concern. Some of the findings of the FDA include but are not limited to:

a. Symptoms of sprue-like enteropathy include severe, chronic diarrhea with substantial weight loss.

b. The enteropathy may develop months to years after starting olmesartan medoxomil, and sometimes require hospitalization.

c. If patients taking olmesartan develop these symptoms and no other cause is found, the drug should be discontinued, and therapy with another antihypertensive started.

d. Discontinuation of olmesartan has resulted in clinical improvement of sprue-like enteropathy symptoms in all patients.

e. Sprue-like enteropathy has not been detected with ARB drugs other than olmesartan.

f. In 2012, a total of approximately 1.9 million patients received a dispensed prescription for olmesartan-containing products from U.S. outpatient retail pharmacies.

g. The FDA identified 23 serious cases in the FAERS presenting as late-onset diarrhea with significant weight loss and, in some cases, with intestinal villous atrophy on biopsy. All patients improved clinically after discontinuation of olmesartan medoxomil, and a positive rechallenge was seen in 10 of the cases.

h. In June 2012, Mayo Clinic researchers published a case series of spruelike enteropathy associated with olmesartan in 22 patients whose clinical presentation was similar to that of the FAERS cases.

i. In May 2013, an article describing patients with villous atrophy and negative serologies for celiac disease reported that some patients without definitive etiologies were characterized as having unclassified sprue. Some of these patients were subsequently found to have villous atrophy associated with olmesartan use.

j. The FDA further investigated the signal of sprue-like enteropathy with olmesartan for a possible ARB class effect using active surveillance data. The FDA found that olmesartan users had a higher rate of celiac disease diagnoses in claims and administrative data than users of other ARBs. Interpretation is limited by the small number of events observed at longer exposure periods and the uncertainty about the validity of codes for

celiac disease, but these results support other data in suggesting a lack of a class effect.

k. Findings of lymphocytic or collagenous colitis and high association with HLA-DQ2/8 suggest a localized delayed hypersensitivity or cell-mediated immune response to olmesartan medoxomil.

55. The Defendants knew, or by the reasonable and careful employment of known scientific methods could have known, and, in the exercise of reasonable care toward patients who would be expected to ingest the olmesartan products, should have known, *inter alia*, that:

a. Studies published in peer-reviewed scientific and medical literature found there may be an association between olmesartan and sprue-like enteropathy;

b. These studies represent the best scientific evidence available for evaluating the association between olmesartan and intestinal problems, including sprue-like enteropathy;

c. Physicians commonly prescribe olmesartan as treatment for hypertension for prolonged periods of six months to a year or more.

d. Clinical trials for the olmesartan drug only lasted up to three months in duration;

e. Sprue-like enteropathy are typically and often experienced chronically over long periods of time; and/or

f. Clinical trials over periods greater than three months would reveal the effects of longer term cumulative exposure to olmesartan.

56. Numerous additional case reports and articles have been published in the past few years documenting intestinal injury to users of olmesartan products, including but not limited to:

a. S.E. Dreifuss, Y. Tomizawa, N.J. Farber, et al., *Spruelike Enteropathy Associated with Olmesartan: An Unusual Case of Severe Diarrhea*. Case Reports in Gastrointestinal Medicine. Epub ahead of print, accepted 20 February 2013.

b. M. DeGaetani, C.A. Tennyson, et al. *Villous Atrophy and Negative Celiac Serology: A Diagnostic and Therapeutic Dilemma*. Am. J. Gastroenterol. 2013 May; 108(5): 647-53.

c. J.A. Nielsen, A. Steephen, M. Lewin. *Angiotensin-II inhibitor (olmesartan)-induced collagenous sprue with resolution following discontinuation of drug*. World J. Gastroenterol. 2013 Oct 28; 19(40): 6928-30 .

d. P.P. Stanich, M. Yearsley, M.M. Meyer. *Olmesartan-associated Sprue-like Enteropathy*. J. Clin. Gastroenterol. 2013 Nov/Dec; 47(10): 894-5.

e. H. Theophile, X.R. David, et al. *Five cases of sprue-like enteropathy in patients treated by olmesartan*. Dig. Liver Dis. 2014 Jan 25. Epub ahead of print.

f. M. Abdelghany, L. Gonzalez, et al. *Olmesartan Associated Sprue-like Enteropathy and Colon Perforation*. Case Reports in Gastrointestinal Medicine. Epub ahead of print, accepted 29 January 2014

g. G. Ianiro, S. Bibb, et al. *Systematic Review: Sprue-Like Enteropathy Associated with Olmesartan*. Ailment. Pharmacol. Ther. 2014; 40: 16-23.

h. M.L. Sanford and A.K. Nagel, *A Review of Current Evidence of Olmesartan Medoxomil Mimicking Symptoms of Celiac Disease.* J. Pharm. Prac. 1-4 (2014).

i. M. Basson, M. Mezzarobba, et al. *Severe Malabsorption Associated with Olmesartan: A French Nationwide Cohort Study.* (Abstract only.)

j. T.H. Tran and H. Li, *Olmesartan and Drug-Induced Enteropathy*. Pharmacovig. Forum, Vol. 39 No. 1 (Jan. 2014).

k. L. Marthey, G. Cadiot, et al. *Olmesartan-associated Enteropathy: Results of a National Survey.* Ailment. Pharmacol. Ther. (Aug. 2014).

FDA Investigates Risk of Cardiovascular Events

57. In 2010, the FDA issued a Drug Safety Communication announcing that the agency was evaluating data from two clinical trials in which patients with type 2 diabetes taking olmesartan had a higher rate of death from a cardiovascular cause compared to patients taking a placebo. The Agency planned to review primary data from the two studies of concern, and was considering additional ways to assess the cardiovascular effects of Benicar®.

58. In 2011, the FDA issued a safety review update as a follow-up to the 2010 FDA Safety Communication. After reviewing the results of these clinical trials, the FDA determined that the benefits of Benicar® continue to outweigh its potential risks when used for treatment of patients with high blood pressure according to the drug label. Daiichi Sankyo agreed to work with the FDA to perform additional studies, as well as

conduct additional analyses of completed clinical studies, to obtain more complete information about the cardiovascular risks or benefits of Benicar® in various clinical settings.

Defendants' False and Misleading Advertising which Omitted and/or Minimized Information about Risks Associated with Olmesartan

59. On information and belief, Daiichi Sankyo paid Forest millions of dollars between 2002 and 2008 to promote Benicar® and Benicar HCT®.

60. At all times relevant to this action, Daiichi Sankyo's olmesartan products were the third highest selling ARB products available on the U.S. market.

61. The U.S. market for hypertension treatment is massive. Approximately 73 million people in the United States age 20 and older have hypertension, about 70 percent of adults with hypertension use medication to treat the condition.

62. On information and belief, Daiichi Sankyo invested heavily in marketing directly to physicians to promote its olmesartan products.

63. On information and belief, the olmesartan products were sold as part of a co-promotion agreement with Forest, a recognized United States pharmaceutical company.

64. On information and belief, Daiichi Sankyo and Forest distributed marketing materials to physicians and other consumers claiming that its olmesartan products were superior, more effective, and safer than other antihypertensive drug products available.

65. In 2006, the FDA found Daiichi Sankyo and Forest's efficacy and safety claims unsubstantiated and false or misleading. According to the FDA and contrary to Daiichi Sankyo' s marketing claims, there was no evidence that Benicar was superior to,

safer than, or more effective than other ARBs. The FDA also found that Daiichi Sankyo and Forest's marketing materials failed to include risk information necessary to qualify its safety and effectiveness claims presented for Benicar® and Benicar HCT®. In addition to omitting important risks from the PI, the materials also minimized the risks it did present, thereby misleadingly signaling to the reader that the risks that were presented were minimal.

66. The FDA ordered Daiichi Sankyo and Forest to cease making these superiority and efficacy claims and to take corrective measures. The corrective measures included discontinuing use of approximately fifty promotional pieces dated all the way to 2002 and dissemination of corrective messages to physicians who received the materials.

67. The promotional materials that were discontinued included, but were not limited to, product monographs that are the full prescribing information for a product, posters, and hospital displays.

68. In 2013, the FDA found a Direct Mail promotional item for Benicar and Benicar HCT submitted by Daiichi Sankyo misleading because it made unsubstantiated efficacy claims associated with Benicar and Benicar HCT in violation of the Federal Food, Drug and Cosmetic Act. Promotional materials are considered misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

69. The FDA requested that Daiichi Sankyo immediately cease the dissemination of violative promotional materials for Benicar® and Benicar HCT®.

Efficacy of Olmesartan Products

70. At all times relevant to this action, Daiichi Sankyo did not conduct any clinical outcome trials that would prove that olmesartan medoxomil is effective in treating conditions associated with the long-term risks of hypertension. In contrast, five of the seven ARBs have performed clinical outcome trials investigating the long-term risks of hypertension, such as heart failure, stroke, and renal nephropathy in patients with Type 2 diabetes mellitus.

Plaintiffs Ingestion of the Olmesartan Product(s)

71. Plaintiff was prescribed BENICAR® by Dr. Gary Peterson located in Duluth, Minnesota.

72. Plaintiff ingested and used the olmesartan product named BENICAR® according to its intended and directed use.

73. While taking the recommended dosage of BENICAR®, Plaintiff developed personal injuries, including but not limited to intestinal diseases/injuries known as sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, or collagenous colitis.

74. The above-named disease manifestations resulted in Plaintiff suffering from chronic diarrhea.

75. After developing these injuries, Plaintiff has suffered from several other ailments that developed and/or worsened as a result of the Plaintiff suffering from chronic diarrhea (and associated symptoms) and/or the physician's attempted various treatments to alleviate this chronic diarrhea.

76. It was and is necessary for Plaintiff's medical conditions to be monitored by physicians and other health care providers to determine sequelae associated with intestinal and/or colonic disease manifestations, as well as severe chronic diarrhea, rapid and substantial weight loss, severe malnutrition, and severe dehydration.

77. Plaintiff's medical conditions necessitated screening, testing, and treatment performed by physicians and other health care providers, which have required and will require Plaintiff to be continually monitored for sequelae associated with such screening, testing, and treatment.

78. Plaintiff has suffered unavoidable, serious and life threatening physical injuries, severe emotional distress, and mental injuries in coping with his physical injuries, and has incurred and expended significant amounts for the medical care, hospitalizations, and medications, required to treat and care for her olmesartan-related disease, pain, and suffering and will continue to do so long into the future.

COUNT I
PRODUCTS LIABILITY- DEFECTIVE DESIGN

79. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

80. Defendants have a duty to provide adequate warnings and instructions for the olmesartan product (s), to use reasonable care to design a product that is not unreasonably dangerous to users and to adequately test its product.

81. At all times relevant to this action, the Defendants researched, designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted, and sold the olmesartan product(s), placing the drug into the stream of commerce.

82. At all times relevant to this action, the olmesartan product(s), was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a condition that was defective and unreasonably dangerous to consumers, including the Plaintiffs.

83. The olmesartan product ingested by Plaintiff, is defective in its design and/or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

84. The olmesartan product ingested by Plaintiff, as manufactured and supplied, was defective due to, *inter alia*:

a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonable safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;

b. When placed in the stream of commerce, it was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of hypertension;

c. The drug was insufficiently tested;

d. The drug caused harmful side effects that outweighed any potential utility;

e. The drug was not accompanied by adequate instructions and/or warnings to fully apprise the consumers, including the Plaintiff, of the full nature and extent of the risks and side effects associated with its uses, thereby rendering the Defendants liable to the Plaintiff, individually and collectively;

f. Defendants failed to adequately instruct on the length of time an individual should be allowed to continue using the drug;

g. Defendants were aware at the time the olmesartan products were marketed that chronic, long-term intake of the olmesartan products would result in an increased risk of gastrointestinal injury, sprue-like enteropathy, chronic diarrhea, weight loss, hospitalization(s) related to dehydration and malnutrition, vomiting, and/or severe nausea;

h. Defendants were aware at the time that the drug was marketed that chronic, long-term use would result an increased risk of bodily injuries;

i. There was inadequate post-marketing surveillance; and/or

j. There were safer alternative designs and formulations that were not utilized.

85. The olmesartan product(s), was expected to reach, and did reach, users and/or consumers, including Plaintiffs, without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.

86. Plaintiffs used the olmesartan product(s), as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

87. The olmesartan product(s) was unreasonably dangerous in that, as designed, it failed to perform safely when used by ordinary consumers, including Plaintiffs, including when it was used as intended and in a reasonably foreseeable manner.

88. The Plaintiff could not, by the reasonable exercise of care, have discovered the defects and perceived their danger before ingestion of the olmesartan product(s).

89. The olmesartan product(s) was unreasonably dangerous and defective in design or formulation for its intended use in that, when it left the hands of the manufacturers and/or supplier, it posed a risk of serious gastrointestinal injury, including sprue-like enteropathy and/or chronic and severe diarrhea, and other serious injury, which could have been reduced or avoided, inter alia, by the adoption of a feasible reasonable alternative design. There were safer alternative methods and designs for the like product.

90. The defects in Defendants' olmesartan product(s) were substantial and contributing factors in causing Plaintiff's injuries.

91. As a direct and proximate result of Defendants' acts and omissions and Plaintiff's ingestion of Defendants' defective product, Plaintiff has suffered serious

physical injuries and has incurred substantial medical costs and expenses to treat and care for her injuries described herein, in addition, she has suffered physical pain and mental anguish, diminished physical abilities and ability to engage in daily activities, and will continue to suffer economic loss, and physical and emotional injuries in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT II
PRODUCTS LIABILITY- FAILURE TO WARN

92. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

93. The olmesartan product ingested by Plaintiff was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff herein, to the dangerous risks and reactions associated with the drug, including severe gastrointestinal injury, sprue-like enteropathy, chronic diarrhea, nausea, malnutrition, dehydration, and/or weight loss.

94. The Plaintiff was administered the olmesartan product(s) for its intended purpose.

95. Neither Plaintiff, nor Plaintiff's physician, knew, nor could they have learned through the exercise of reasonable care, of the risk of severe gastrointestinal injury associated with or caused by the olmesartan product.

96. Defendants, as the manufacturer or distributor of prescription drug products, were responsible for researching, developing, designing, testing, manufacturing, inspecting, labeling, marketing and promoting the olmesartan products that they distributed, sold and otherwise released into the stream of commerce, and therefore had a duty to adequately warn of the risks associated with the use of their respective products.

97. Defendants had a continuing duty to warn the Plaintiff of the dangers associated with the olmesartan products.

98. Defendants, as manufacturers, sellers, or distributors of a prescription device, are held to the knowledge of an expert in the field.

99. The dangerous propensities of the olmesartan products, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

100. Each of the Defendants knew or should have known that the limited warnings disseminated with the olmesartan products were inadequate.

101. Defendants communicated to physicians information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions,

that would enable doctors to prescribe the drug safely for use by his or her patients for the purposes for which it is intended, including commonly employed long term antihypertensive drug therapy. In particular, the Defendants disseminated information that was inaccurate, false and misleading and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with such use of olmesartan product; continued to aggressively promote the olmesartan products, even after it knew or should have known of the unreasonable risks from long term use; and overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the minimal warnings it did disseminate.

102. Owing to these deficiencies and inadequacies, the olmesartan product as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants was unreasonably dangerous and defective.

103. As a direct and proximate result of the Defendants' failure to provide adequate warnings about the dangers associated with the drug, the Plaintiff has suffered and permanent physical injuries, emotional distress, economic losses and other damages to be proved at trial.

104. By reason of the foregoing, Defendants are liable to Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and Plaintiff's healthcare provider about the increased risks of serious injury caused by olmesartan.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages,

exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT III
GROSS NEGLIGENCE

105. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

106. Defendants had a duty to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of the olmesartan product(s), including a duty to ensure that it did not cause users to suffer from unreasonable and dangerous side effects.

107. Defendants failed to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendants' product, olmesartan, in that Defendants knew or should have known that taking the olmesartan product(s), caused unreasonable and life-threatening injuries, as alleged herein.

108. Defendants were grossly negligent under the circumstances and breached their duty of care in numerous ways, including the following:

a. failing to test the olmesartan products properly and thoroughly before releasing the drug to the market;

b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of the olmesartan products;

c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of the olmesartan products which indicated risks associated with its use;

d. failing to conduct adequate post-market monitoring and surveillance of the olmesartan products;

e. failing to conduct adequate analysis of adverse event reports;

f. designing, manufacturing, marketing, advertising, distributing, and selling the olmesartan products to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the olmesartan products and without proper instructions to avoid the harm that could foreseeably occur as a result of using the drug;

g. failing to exercise due care when advertising and promoting the olmesartan products;

h. recklessly continuing to manufacture, market, advertise, and distribute the olmesartan products after Defendants knew or should have known of the risks of serious injury and/or death associated with using the drug;

i. failing to use due care in the preparation and development of the olmesartan products to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

j. failing to use due care in the design of the olmesartan products to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

k. failing to conduct adequate pre-clinical testing and research to determine the safety of the olmesartan products;

l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of the olmesartan products, while Defendants knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of the olmesartan products for causing serious injury and death as alleged herein in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendants to the need to change the drug's warnings or to withdraw it from the market altogether;

m. failing to completely, accurately, and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, their doctors, other consumers, the medical community, and the FDA;

n. failing to accompany the olmesartan products with proper warnings regarding all possible adverse side effects associated with the use of the same;

o. failing to use due care in the manufacture, inspection, and labeling of the olmesartan products to prevent the aforementioned risk of injuries to individuals who used the drug;

p. failing to use due care in the promotion of the olmesartan products to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

q. failing to use due care in the sale and marketing of the olmesartan products to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

r. failing to use due care in the selling of the olmesartan products to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

s. failing to provide adequate and accurate training and information to the sales representatives who sold the drug;

t. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of the olmesartan products;

u. failing to educate healthcare providers and the public about the safest use of the drug;

v. failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and

w. being otherwise grossly negligent.

109. Although Defendants knew, or recklessly disregarded, the fact that Defendants' olmesartan products caused potentially severe gastrointestinal side effects, Defendants continued to market the olmesartan products to consumers, including Plaintiff, without disclosing these side effects.

110. Defendants knew and/or consciously or recklessly disregarded the fact that consumers such as Plaintiff would suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

111. Defendants knew of, or recklessly disregarded the defective nature of Defendants' olmesartan products as set forth herein, but continued to design, manufacture, market, and sell Defendants' olmesartan products, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in

conscious and/or reckless disregard of the foreseeable harm caused by Defendants' olmesartan products.

112. As a direct and proximate consequence of Defendants' gross negligence, the Plaintiff sustained injuries and damages alleged herein including severe physical gastrointestinal injuries, severe emotional distress, economic losses and other damages to be proved at trial.

113. By reason of the foregoing, Defendants are liable to Plaintiff for damages as a result of their gross negligence.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT IV
NEGLIGENCE

114. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

115. Defendants, directly or indirectly, caused the olmesartan products to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff.

116. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and/or distribution of the olmesartan products, including the duty to take all reasonable steps

necessary to manufacture, label, promote and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

117. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed and/or sold the olmesartan products, Defendants knew, or in the exercise of reasonable care should have known, that their products were defective, dangerous, and otherwise highly harmful to Plaintiff.

118. Defendants knew, or in the exercise of reasonable care should have known, that the use of the olmesartan products could cause or be associated with severe gastrointestinal injury, sprue-like enteropathy, chronic severe diarrhea, nausea, vomiting, dehydration, malnutrition and other serious injury, and thus created a dangerous and unreasonable risk of injury to users of the products.

119. Defendants knew from its own investigations, including analysis of sales statistics, adverse event reporting, and/or scientific studies published in peer-reviewed medical journals, that many physicians were unaware of the extent of these risks posed by the olmesartan products.

120. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, advertisement, packaging, testing, quality assurance, quality control, sale, and distribution of the olmesartan products in interstate commerce, in that Defendants knew and had reason to know that a consumer patient's use and ingestion of the product(s) created a significant risk of suffering unreasonably dangerous health related

side effects, severe gastrointestinal injury, sprue-like enteropathy, chronic severe diarrhea, nausea, vomiting, dehydration, malnutrition and other serious injury.

121. Defendants were further negligent in that they manufactured defective products containing the drug olmesartan medoxomil, knew and were aware of the defect inherent in the products, failed to act in a reasonably prudent manner in marketing the products, and failed to provide adequate warnings of the products' defects.

122. Defendants were further negligent and breached their continuing duty of pharmacovigilance with respect to Plaintiffs in that Defendants, through clinical trials and other adverse event reports, learned that there were serious problems with the use of the olmesartan products and failed to inform physicians, regulatory agencies, and the public of this risk. Defendants had the means and the resources to perform their pharmacovigilance duties for the entire time the olmesartan products have been on the market in the United States.

123. Defendants' negligence included, but not limited to, the following acts and omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling and/or distributing the olmesartan products without thorough and adequate pre- and post-market testing of the product;

b. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the olmesartan products while negligently and/or intentionally concealing and failing to disclose the

results of clinical trials and tests regarding use of the olmesartan products, which demonstrated the risk of serious harm associated with the use of olmesartan products;

c. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of the olmesartan products;

d. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the olmesartan products were safe for its intended use;

e. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew or had reason to know that the olmesartan products were indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users in the form of intestinal damage and other serious illnesses;

f. Failing to warn plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative antihypertensive medications available to plaintiff and other consumers;

g. Declining to make or propose any changes to the olmesartan products' labeling or other promotional materials that would alert physicians and the medical community to the risks of the olmesartan products;

h. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and consume the olmesartan products;

i. Advertising, marketing, and recommending the use of the olmesartan products, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected, associated or caused in the use of the olmesartan products;

j. Representing that the olmesartan products were safe for its intended use when in fact, Defendants knew or should have known that the products were not safe for their intended purpose;

k. Failing to advise physicians, the medical community, or patients taking the olmesartan products, that its statements regarding the safety of its products were inaccurate;

l. Failing to disclose to Plaintiff and Plaintiff's prescribing physician(s), through the prescribing information for the olmesartan products, about the risk of developing severe gastrointestinal injury such as sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, and collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and/or dehydration;

m. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective antihypertensive drugs were

available for use to treat hypertension for which the olmesartan products were manufactured;

n. Failing to reference the chronic nature and severity of the adverse reactions provided in its label, including developing severe gastrointestinal injury such as sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, and collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration;

o. Continuing to disseminate information to physicians which indicate or imply that the olmesartan products are not unsafe for treatment of hypertension;

p. Continuing manufacture and sale of the olmesartan products with the knowledge that the products were unreasonably unsafe and dangerous, and failed to comply with FDA regulations and policy;

q. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the olmesartan products so as to avoid the risk of serious harm associated with the use of the olmesartan products as an antihypertensive medication;

r. Advertising, marketing, promoting and/or selling the olmesartan products for uses other than as approved and indicated in the product's label;

s. Failing to design and manufacture the olmesartan products so as to ensure the products were at least as safe and effective as other antihypertensive drugs on the market;

t. Failing to ensure the products were accompanied by proper and accurate warnings about the possible adverse side effects associated with the use of the olmesartan products and that such use created a risk of developing severe gastrointestinal injury such as, sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, that could be life-threatening; and/or

u. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance, to determine the safety of the olmesartan products.

124. Defendants knew or should have known that it was foreseeable that consumers such as plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturer, marketing, labeling, distribution and sale of the olmesartan products.

125. Plaintiff did not know the nature and extent of the injuries that would result from ingestion and use of the olmesartan product(s).

126. Defendants' negligence was the proximate cause of the injuries, harm, and economic loss that Plaintiffs have suffered and will continue to suffer into the future.

127. As a result of Defendants' acts and omissions described in this Complaint, Plaintiff was proximately caused to suffer the serious and dangerous side effects of the olmesartan products, including but not limited to severe gastrointestinal injury such as sprue-like enteropathy, chronic diarrhea, weight loss, nausea, vomiting, dehydration and malnutrition. Plaintiff also suffered as a result of Defendants' acts and omissions, physical pain and mental anguish, significantly diminished physical abilities and the need for future medical monitoring and treatment of injuries related to Plaintiffs' ingestion of the olmesartan product(s) and the resulting medical conditions and injury.

128. As a proximate result of Defendants' acts and omissions and Plaintiff's ingestion of Defendants' defective product, Plaintiff has suffered serious physical injuries and has incurred substantial medical costs and expenses to treat and care for the injuries described herein. As a further direct and proximate result of Defendants' acts and omissions, Plaintiff has suffered serious and physical and emotional injuries and economic loses, and will continue to suffer economic loss and physical and emotional injuries in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT V
NEGLIGENCE *PER SE*

129. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

130. Defendants have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, and warning of risks and dangers of the olmesartan products.

131. Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, *inter alia*, failing to report each adverse drug experience concerning the olmesartan products that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by Defendants, failing to promptly investigate all adverse drug experiences concerning the olmesartan products that are the subject of these postmarketing 15-day Alert reports, failing to submit follow up reports within 15 calendar days of receipt of new information or as requested by the FDA, and, if additional information is not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information. Defendants' failure to meet these requirements is evidence of defendants' negligence and constitutes negligence *per se*.

132. As a direct and proximate result of Defendants' statutory and regulatory violations, Plaintiff, a member of the class of persons protected by the above-mentioned

statute, suffered, and will continue to suffer, injuries and is entitled to compensatory damages, and exemplary and punitive damages together with interest, and the cost of suit and attorneys' fees, in an amount to be proved at trial.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VI
NEGLIGENT MISREPRESENTATION

133. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

134. Defendants had a duty to accurately and truthfully represent to the medical community, the FDA, and consumers, including Plaintiff, the truth regarding Defendants' claims that the olmesartan products had been tested and found to be safe and effective for hypertension treatment. The misrepresentations made by Defendants, in fact, were false at the time the misrepresentations were made by Defendants, and Defendants had no reasonable basis to make their representations.

135. Defendants failed to exercise ordinary care in making their representations concerning the olmesartan products and their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce.

136. Defendants engaged in a campaign of over-promoting the olmesartan products in written marketing literature, in written product packaging, and in direct-to-

consumer advertising via written advertisements and television commercial ads. Defendants over-promoted by touting the safety and efficacy of the olmesartan products while concealing, misrepresenting, actively downplaying the serious, severe, and life-threatening risks of harm to users of olmesartan products, when compared to comparable or superior alternative drug therapies, including the risk of sustaining damage to the intestine, developing chronic and severe diarrhea, dehydration, and malnutrition as a result of ingestion of olmesartan.

137. Defendants negligently misrepresented the olmesartan products' risk of unreasonable, dangerous, adverse side effects.

138. As a direct and proximate result of Defendants' acts and omissions described herein, and Plaintiff's ingestion of Defendants' defective product, Plaintiff has suffered serious physical injuries and has incurred substantial medical costs and expenses to treat and care for the injuries described herein. As a further direct and proximate result of Defendants' acts and omissions, the Plaintiff suffered serious physical and emotional injuries, and will continue to suffer these injuries and incur economic losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VII
FRAUDULENT CONCEALMENT

139. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

140. Throughout the relevant time period, Defendants knew that the olmesartan products were defective and unreasonably unsafe for their intended purpose.

141. Defendants fraudulently concealed from or failed to disclose to or warn Plaintiffs, physicians, and the medical community that the olmesartan products were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

142. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the olmesartan products because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of the olmesartan products;

b. Defendants knowingly made false claims about the safety and quality of the olmesartan products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective nature of the olmesartan products from Plaintiffs.

143. The facts concealed or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use the olmesartan products.

144. The facts concealed or not disclosed by Defendants were not reasonably ascertainably by Plaintiff or Plaintiff's physician.

145. Defendants intentionally concealed or failed to disclose the true defective nature of the olmesartan products so that Plaintiff would request and purchase the olmesartan products, and so that Plaintiff's healthcare providers would dispense, prescribe, and recommend the olmesartan products, and Plaintiff justifiably acted or relied upon, to Plaintiff's detriment, the concealed or non-disclosed facts as evidenced by Plaintiff's purchase of the olmesartan products.

146. As a direct and proximate result of Defendants' foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, inter alia, severe gastrointestinal injury, sprue-like enteropathy, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, and/or other severe and personal injuries.

147. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has incurred in the past and will incur in the future, health care, incidental, and related expenses.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VIII
CONSTRUCTIVE FRAUD

148. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

149. Defendants are in a unique position of knowledge concerning the quality, safety, and efficacy of the olmesartan products, which knowledge is not possessed by Plaintiff or Plaintiff's physicians.

150. Despite their unique knowledge regarding the defective nature of the olmesartan products, Defendants suppressed, concealed, omitted, or misrepresented information to Plaintiff, the medical community, or the FDA, concerning the severity of risks and the dangers inherent in the recommended and marketed use of the olmesartan products, as compared to safer alternative products.

151. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the olmesartan products carried a risk of severe gastrointestinal injury and/or sprue-like enteropathy, which other products in their class do not have. Instead, Defendants have misrepresented the safety and efficacy of the olmesartan products, in order to convince consumers and physicians to use their olmesartan products.

152. Plaintiff and the medical community reasonably relied upon Defendants' misrepresentations.

153. As a direct and proximate result of Defendants' foregoing acts and omissions, Plaintiff sustained serious injury, including severe gastrointestinal injury,

sprue-like enteropathy, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, and/or other severe and personal injuries, physical pain and mental anguish.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT IX
VIOLATION OF MINNESOTA CONSUMER PROTECTION LAWS

154. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

155. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of olmesartan products to Plaintiff.

156. Defendants engaged in unfair, unconscionable, deceptive, fraudulent and misleading acts or practices in violation of MINNESOTA's consumer protection laws, *M.S.A. §325.*

157. Through their false, untrue and misleading promotion of olmesartan products, Defendants induced Plaintiff to purchase and/or pay for the purchase of olmesartan products.

158. Defendants misrepresented the alleged benefits and characteristics of olmesartan products; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of olmesartan products; misrepresented

the quality and efficacy of olmesartan products as compared to other alternatives; misrepresented and advertised that olmesartan products was of a particular standard, quality, or grade that it was not; misrepresented olmesartan products in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff would have switched from olmesartan products to another antihypertension medication and/or chosen not to purchase and/or reimburse for purchases of olmesartan products; advertised olmesartan products with the intent not to sell them as advertised; and otherwise engaged in fraudulent and deceptive conduct.

159. Defendants' conduct misled, deceived and damaged Plaintiff, and Defendants' fraudulent, misleading and deceptive conduct was perpetrated with an intent that Plaintiff's rely on said conduct by purchasing and/or paying for purchases of olmesartan products. Moreover, Defendants knowingly took advantage of Plaintiff, who was reasonably unable to protect their interests due to ignorance of the harmful adverse effects of olmesartan products.

160. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable and substantially injurious to Plaintiff and offends the public conscience.

161. Plaintiff purchased olmesartan products primarily for personal, family, or household purposes.

162. As a result of Defendant's violative conduct, Plaintiff purchased and/or paid for purchases of olmesartan products that were not made for resale.

163. Defendant engaged in unfair competition or deceptive acts or practices in violation of MINNESOTA Stat. § M.S.A. §325, *et seq*.

164. As a proximate result of Defendants' misrepresentations and omissions, Plaintiff has suffered ascertainable losses, in an amount to be determined at trial.

165. By reason of the foregoing, Defendants are liable to Plaintiff for damages as a result of their violations MINNESOTA Stat. § M.S.A. §325, *et seq*. prohibiting consumer fraud and deceptive and unfair trade practices

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT X
BREACH OF EXPRESS WARRANTIES

166. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

167. Defendants expressly warranted that the olmesartan products which they designed, manufactured, sold, distributed, promoted, packaged, marketed or otherwise placed in the stream of commerce were merchantable, reasonably fit for use, safe for their intended purposes, adequately tested, and did not produce any unwarned-of dangerous side effects.

168. Defendants breached expressed warranties with respect to olmesartan products in the following particulars:

a. Defendants represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that olmesartan products were safe, and fraudulently withheld and concealed information about the substantial risks of serious gastrointestinal injury associated with using olmesartan products;

b. Defendants represented that olmesartan products were as safe, and/or safer than other alternative medications and fraudulently concealed information that demonstrated that olmesartan products were not safer than alternatives available on the market; and

c. Defendant represented that olmesartan products was more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy of the drug.

169. Olmesartan products do not conform to Defendants' express representations because they are not safe or well-tolerated, they may cause unwarned-of side effects such as severe gastrointestinal injuries, they were not adequately tested, and they are not more efficacious than alternative antihypertension treatments and methods.

170. At all relevant times, olmesartan products did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

171. Plaintiff, Plaintiff's physicians, other consumers, and the medical community relied upon Defendants' express warranties, resulting in Plaintiff's ingestion of the drug.

172. As a direct and proximate consequence of Defendants' breach of their warranties, the Plaintiff sustained injuries and damages alleged herein including severe and permanent physical injuries, severe emotional distress, economic losses and other damages to be proved at trial.

173. By reason of the foregoing, Defendants are liable to Plaintiff for damages as a result of its breach of warranty.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT XI
BREACH OF IMPLIED WARRANTIES

174. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

175. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold olmesartan products.

176. At all relevant times, Defendants intended that olmesartan products be used in the manner that Plaintiff in fact used it.

177. Defendants impliedly warranted olmesartan products to be of merchantable quality, safe and fit for the use for which Defendants intended it, and Plaintiff in fact used it.

178. Defendants were aware that consumers, including Plaintiff, would use olmesartan products as an antihypertension treatment; which is to say that Plaintiff was a foreseeable user of Defendants' olmesartan products.

179. Defendants knew, or had reason to know, that Plaintiff's physicians would rely on Defendants' judgment and skill in providing olmesartan products for their intended use.

180. Plaintiff and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendant as to whether olmesartan was of merchantable quality, safe and fit for its intended use.

181. The drug was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

182. Defendants breached various implied warranties with respect to olmesartan products, including the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that olmesartan products were safe, and fraudulently withheld and concealed information about the substantial risks of serious gastrointestinal injury associated with using olmesartan products;

b. Defendants represented that olmesartan products were as safe, and/or safer than other alternative medications and fraudulently concealed information

that demonstrated that olmesartan products were not safer than alternatives available on the market; and

c. Defendants represented that olmesartan products were more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy of the drugs.

183. In reliance upon Defendants' implied warranty, Plaintiff used the olmesartan product as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

184. Defendants breached their implied warranty to Plaintiff in that the olmesartan product was unreasonably dangerous, defective, and unfit for the ordinary purposes for which it was used. It was not of merchantable quality, safe and fit for its intended use, or adequately tested.

185. Defendants breached the implied warranty that the olmesartan product was of merchantable quality and fit for such use in violation of MINNESOTA M.S.A. §336.2-314.

186. As a direct and proximate consequence of Defendants' breach of their warranty, the Plaintiff sustained injuries and damages alleged herein including severe gastrointestinal injuries, severe emotional distress, economic losses and other damages to be proved at trial.

187. By reason of the foregoing, Defendants are liable to Plaintiff for damages as a result of their breach of implied warranty.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT XII
UNJUST ENRICHMENT

188. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

189. At all times relevant to this action, Defendants were the manufacturers, sellers, distributors, or promoters of the olmesartan products.

190. Plaintiff purchased the olmesartan product(s) for the purpose of treating hypertension in reliance upon the Defendants' representations of the safety and efficacy of the product.

191. Defendants have accepted payments from Plaintiff and other consumers for the purchase of the olmesartan product(s).

192. Plaintiff did not receive the safe and effective antihypertensive drug for which Plaintiff paid, and equity demands that Defendants be disgorged of their profits received from the defective drug and their own deception regarding the safety and efficacy of the drug.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages,

exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT XIII
PUNITIVE DAMAGES

193. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

194. Plaintiffs are entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the olmesartan products. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of the olmesartan products, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting the olmesartan products, despite Defendants' knowledge and awareness of the serious side effects and risks associated with the olmesartan products.

195. Defendants had knowledge of, and were in possession of evidence demonstrating that the olmesartan products caused serious side effects. Notwithstanding Defendants' knowledge of the serious side effects of the olmesartan products, Defendants continued to market the drug products by providing false and

misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the olmesartan products.

196. Although Defendants knew or recklessly disregarded the fact that the olmesartan products cause debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute the olmesartan products to consumers, including Plaintiffs, without disclosing these side effects when there were safer alternative methods for treating hypertension.

197. Defendants failed to provide warnings that would have dissuaded physicians from prescribing the olmesartan products and consumers from purchasing and ingesting the olmesartan product(s), thus depriving both from weighing the true risks against the benefits of prescribing, purchasing or consuming the olmesartan products.

198. Defendants knew of the olmesartan products' defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell and/or promote the drug as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in a conscious or negligent disregard of the foreseeable harm caused by the olmesartan products.

199. The aforementioned conduct of Defendants was committed with knowing, conscious, and deliberate disregard of the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in the amount appropriate to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Awarding Plaintiffs compensatory damages against Defendants in an amount sufficient to fairly and completely compensate Plaintiff(s) for all damages;

B. Awarding Plaintiffs treble damages against Defendants so to fairly and completely compensate Plaintiffs for all damages, and to deter similar wrongful conduct in the future;

C. Awarding Plaintiffs punitive damages against Defendants in an amount sufficient to punish Defendants for its wrongful conduct and to deter similar wrongful conduct in the future;

D. Awarding Plaintiffs costs and disbursements, costs of investigation, attorneys' fees and all other relief available under applicable law;

E. Awarding that the costs of this action be taxed to Defendants; and

F. Awarding such other and further relief as the Court may deem just and proper.

JURY DEMAND

The Plaintiffs hereby request a trial by jury, pursuant to Rule 38 of the Federal Rules of Civil Procedure, on all claims and issues so triable.

Dated: January 27, 2015

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